IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

UNITED STATES OF AMERICA, *et al.*,	
Plaintiffs,	**CIVIL ACTION NUMBERS:**
v.	**1:09-cv-0013 (CMH/TCB)**
	1:11-cv-1054 (CMH/TCB)
HCR MANORCARE, INC., *et al.*,	**1:14-cv-1228 (CMH/TCB)**
Defendants.	

DEFENDANTS HCR MANORCARE, INC., MANOR CARE, INC., HCR MANOR CARE SERVICES, LLC, AND HEARTLAND EMPLOYMENT SERVICES, LLC'S REBUTTAL BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT OF THE UNITED STATES

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I. INTRODUCTION AND SUMMARY OF REBUTTAL ARGUMENT

After five years of investigating this case, the Department of Justice still has failed to adequately plead a False Claims Act ("FCA") case because, as a matter of law, it has not alleged an objectively false claim, nor has it identified in its Complaint individuals who committed objectively fraudulent conduct. Instead of addressing these fundamental issues, and in an apparent effort to convince the Court that the Medicare program will fail if the Court dismisses this Complaint, the government stretches Defendants' arguments to ridiculous extremes that are not relevant to this Complaint. The issue for the Court is not whether the government can adequately plead a medical necessity therapy case under any circumstances, but whether it did so in this case. It did not, as evidenced by the government's complete failure to mention, let alone address, its own regulation stating that clinical disagreements over therapy assessments by skilled nursing facilities ("SNFs") are not false statements. *See* 42 C.F.R. § 483.20(j)(2); Defs.' Mot. to Dismiss 13-16 (ECF No. 117) ("Motion" or "Mot."). This failure is a concession by the government that its regulation controls, and as such, the clinical disagreements contained in this Complaint about what is reasonable and necessary therapy cannot as a matter of law form the basis of this FCA case.[1]

Throughout the Opposition, the government primarily regurgitates the Complaint, still failing to identify where in the Complaint it has adequately alleged any objective standard by which the purported representative examples of therapy were unreasonable and unnecessary. Although "reasonable" and "necessary" are the conclusory regulatory words parroted by the

[1] Defendants have not said that the government could not adequately plead a case for fraudulent over-delivery of therapy. For example, 24 hours of therapy in a single day could not form the basis of a legitimate clinical disagreement. *See* U.S. Opp'n Mot. Dismiss 9 (ECF No. 121) ("Opposition" or "Opp'n"). But this Complaint alleges nothing of the sort, instead arbitrarily claiming fraud for disagreements over minutes, not hours of therapy, per day.

government, these words do not satisfy the requirement that the defendants be advised of the standard used by the government to determine the line where clinical therapy becomes fraud.

Moreover, the government cannot remedy its failure to identify specific individuals in the Complaint who submitted false claims by simply identifying three individuals in its Opposition. First, the Complaint itself does not contain a single particularized allegation that any of these three individuals filed or caused the filing of a false claim, but instead recites a litany of normal business activities occurring in any business enterprise. Second, regardless of the conduct of these three individuals, if specifically identified therapists did not knowingly and fraudulently deliver therapy, an assertion not contained in the Complaint, the conduct of the three individuals identified in the Opposition is irrelevant because there could not have been a false claim.

II. THE GOVERNMENT IGNORES DEFENDANTS' ARGUMENTS AS TO THE LACK OF OBJECTIVE FALSITY AND SCIENTER AND INSTEAD RESPONDS TO EXTREME CHARACTERIZATIONS OF DEFENDANTS' POSITIONS.

A. The Government Fails to Respond to the Fact that Its Regulatory Provision Expressly States that Clinical Disagreements are "Not Material and False Statements."

The Opposition does not contain a single reference to 42 C.F.R. § 483.20(j)(2), which the Defendants primarily rely on and which provides that clinical disagreements regarding rehabilitation therapy assessments do not constitute material and false statements. *See* Mot. 13-16. The government's failure to respond concedes this issue, that as a matter of law, the government's disagreements with the amount of therapy actually delivered, the cost of which was incurred by the Defendants, cannot convert the Defendants' submissions for payment to false claims. *See Intercarrier Commc'ns, LLC v. Kik Interactive, Inc.*, No. 12-771, 2013 WL 4061259, at *3 (E.D. Va. Aug. 9, 2013) (finding plaintiff's failure to respond to defendant's argument that the court lacked general jurisdiction "effectively conced[ed]" the issue (quoting *Cureton v. U.S. Marshal Serv.*, 322 F. Supp. 2d 23, 27 (D.D.C. 2004) ("When a plaintiff files a

response to a motion to dismiss but fails to address certain arguments made by the defendant, the court may treat those arguments as conceded even when the result is dismissal of the case.")).

The core allegation in the Complaint is that the Defendants over-delivered therapy and reported the unnecessary therapy minutes in the minimum data sets ("MDS"), making those MDS submissions false. *See* Compl. ¶¶ 58-63, 219. This allegation represents a clinical disagreement between the government and the licensed professionals who ordered and delivered the therapy. But the government ignores the fact that the regulation it relies upon governing the MDS process, *see* 42 C.F.R. § 483, expressly excludes such disagreements from being "false and material." *See* 42 C.F.R. § 483.20(j)(2). This regulation provides an explicit protection to skilled nursing facilities and their staff that is consistent with CMS's recognition that reasonable minds may disagree as to what is "reasonable and necessary" when making patient-specific clinical determinations as to the frequency and duration of skilled rehabilitation therapy based on MDS clinical assessments. *See* 62 Fed. Reg. 67,174, 67,202-03 (Dec. 23, 1997); Medicare Benefit Policy Manual (CMS Pub. 102), Ch. 8, § 30.4; *see also United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006); *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012).

The opinion in *United States ex rel. Martin v. Life Care Centers of America* ("*Martin*"), which the government primarily relies on in the Opposition, does not rescue the government from this regulation. No. 08-00251 (E.D. Tenn Aug. 14, 2015). *Martin* is different in at least two material respects from this case.[2] First, in *Martin*, the government alleged that defendant Life Care Centers of America ("LCCA") pressured physicians to falsely certify rehabilitation

[2] Moreover, the opinion of a single court in Tennessee is not binding on this court.

therapy, an allegation that the *Martin* court relied upon as a critical fact in its opinion. *See id.* at 19. There is no such allegation here concerning physicians. Second, it is clear from the opinion in *Martin* that the defendant did not cite to or rely on 42 C.F.R. § 483.20(j)(2), and as such, the court in *Martin* did not have the opportunity to consider this critical legal issue.

Defendants respectfully maintain that the government concedes by its silence the applicability of 42 C.F.R. § 483.20(j)(2), has not cited to a single case that contradicts the applicability of this regulatory provision to this Complaint, and as such, has pled a case that is defective as a matter of law and should be dismissed.

B. The Government Fails to Provide Legal Grounds to Support Its Complaint.

Rather than oppose Defendants' actual arguments, the government instead mischaracterizes those arguments and then responds to extreme and distorted interpretations of them. The government suggests that Defendants' Motion argued that unnecessary medical services can *never* give rise to FCA liability. Opp'n 4. Defendants did not assert that there can *never* be an FCA violation for unnecessary medical claims. *See* Mot. 13-16. Although in certain cases subjective determinations may not "automatically exclude [claims] from liability under the FCA," *United States ex rel. Landis v. Hospice Care of Kansas, LLC,* No. 06-2455, 2010 WL 5067614, at *4 (D. Kan. Dec. 7, 2010), the government has failed as a matter of law to plead objective falsity under the applicable skilled rehabilitation therapy regulations. *See* Mot. 13-16. Indeed, federal courts have dismissed medical necessity FCA suits in similar circumstances where, as in this case, there is no ability to measure objective falsity, and the clinical determinations of care are subject to legitimate clinical differences of opinion. *See, e.g., United States v. Prabhu*, 442 F. Supp. 2d 1008, 2026 (D. Nev. 2006); *Geschrey*, 922 F. Supp. 2d at 703; *United States ex rel. Haight v. Catholic Healthcare W.*, No. 01-2253, 2007 WL 2330790, at *3 (D. Ariz. Aug. 14, 2007).

The cases cited in the Opposition do not dispute this precedent or undermine this position. For example, the government cites to *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370 (5th Cir. 2004), for the proposition that "claims for medically unnecessary treatment are actionable under the FCA." Opp'n 4. But in *Riley*, the Fifth Circuit recognized the principle "that the FCA requires a statement known to be false" and that "expressions of opinion or scientific judgments about which reasonable minds may differ cannot be false." 355 F.3d at 376. In *Riley*, the complaint alleged that physicians and hospital staff schemed to admit and upgrade transplant patients. *Id.* Here, the Complaint alleges no misconduct of physicians in certifying, recertifying or ordering therapy for patients. The government also cites to *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 700-01 (2d Cir. 2001), for the proposition that "claims for medically unnecessary services are 'false' under the FCA." Opp'n 4. But *Mikes* does not establish that the medically unnecessary claims in this case are adequately pled; indeed, the Second Circuit affirmed dismissal of claims that certain treatments were not medically necessary based on an allegation that they did not conform to a particular standard of care. 274 F.3d at 701. Moreover, *Riley* and *Mikes* were not therapy cases, and as such 42 C.F.R. § 483.20(j)(2) was not applicable. In addition to these factual and regulatory distinctions, both cases predate the Supreme Court decision in *Iqbal*, which strengthened federal pleading standards to avoid costly litigation of claims that are implausible. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-81 (2009) (pleadings must allege facts to support a "reasonable inference that the defendant is liable" and cannot do so by pleading legal conclusions).

The government also relies on *United States ex rel. Lawson v. Aegis Therapies, Inc*., No. 10-0072, 2013 WL 5816501 (N.D. Ga. Oct. 29, 2013),[3] Opp'n 6, but ignores the subsequent order in *Lawson* that established precisely why the Complaint here fails. In granting summary judgment to the defendant in a case intervened by the government, the *Lawson* court held that in determining what therapy was reasonable and necessary the government's experts used the wrong standard of "significant practical improvement," whereas the correct standard is "expectation of material improvement," which is lower. *United States ex rel. Lawson v. Aegis Therapies, Inc.*, No. 10-0072, 2015 WL 1541491, at *7-9 (S.D. Ga. Mar. 31, 2015). Here, the Complaint alleges no standard at all against which the government's medical necessity determinations have been made. Absent such an allegation, the conclusory statements by the government regarding what is unreasonable and unnecessary cannot meet the *Iqbal* standard.

Nor does the government's reliance on hospice cases save this Complaint. *See* Opp'n 5-6 (citing *Landis*, 2010 WL 5067614 and *United States v. Vitas Hospice Servs., LLC*, No. 13-00449, (W.D. Mo. Sept. 30, 2014)). Each hospice complaint alleged detailed facts relating to lack of medical necessity that could be measured objectively.[4] Moreover, hospices are governed by an entirely different regulatory framework, which does not include 42 C.F.R. § 483.20(j)(2).

The government shrugs off *Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006), without attention to its facts. In *Prabhu*, unlike here, the government's complaint alleged a particular

[3] The government mistakenly cites *Lawson* as *United States ex rel. Reid. See* Opp'n 6. The plaintiff-relator in that case was named Reid Lawson.

[4] In *Landis*, the relator alleged that physicians could not exercise their medical judgment regarding hospice because the defendant provided the physicians with false information. 2010 WL 5067614, at *3-4. Here, there is no allegation that the Defendants lied to physicians or that physicians were otherwise unable to exercise their independent clinical judgment. In *Vitas Hospice*, the government alleged that (1) patients were not qualified, (2) defendant billed for services not performed, and (3) defendant misrepresented services provided. No. 13-00449, at *9. None of these circumstances are alleged in this case.

standard for lack of medical necessity and, specifically, that services were not medically necessary "because no further improvement . . . could reasonably be expected for those patients at the time the services were rendered." *Id.* at 1020. Although the *Prabhu* court found a lack of evidence in granting summary judgment to the defendant, it also recognized, as argued in the Motion at 13, that claims are not false where reasonable persons can disagree whether a service was properly billed to the government. *Id*. at 1026. In this case, the government has pled contrary to its own regulations and without articulating *any* standard by which it determined a lack of medical necessity, leaving a mystery for the Court and a failure to adequately advise Defendants of the claims.

The government further mischaracterizes and misconstrues Defendants' argument to suggest that "so long as the provider asserts that the claim is necessary…any treatment, no matter how unnecessary, could be charged to Medicare…" Opp'n 7. Defendants never said any such thing. First, as stated above, Defendants maintain that this Complaint is defective, and do not contend that every medical necessity case would be impossible to plead correctly. Second, dismissing this Complaint will not render the government without recourse, as it has administrative tools and established review procedures to disallow or challenge medical necessity of claims–even when based on clinical disagreements. *See* 42 C.F.R. § 405(I), 42 U.S.C. § 1395gg.

C. The Government Mischaracterizes Defendants' Argument Concerning Physician Certifications.

Defendants never argued that physician certifications insulate them from FCA violations. *See* Opp'n 8-9. Rather, in the absence of allegations of falsity related to physician orders and certifications, Defendants maintain that the government must allege more than clinical disagreements as to the amount of therapy provided. Mot. 13-16. The Complaint does not allege

falsity surrounding physician certifications or re-certifications, pressure on physicians, physician complicity, false physician orders or certifications, or physician complaints regarding the rehabilitation therapy provided by Defendants. Likewise, the Complaint does not identify any therapists who fraudulently provided too much therapy. If the Complaint does not accuse physicians of fraud in ordering, certifying or re-certifying the care (which it does not) and does not accuse specific therapists of fraudulently delivering too much care (which it does not) as a matter of law, the Complaint does not plead a false claim.[5]

D. The Skilled Rehabilitation Regulations and Guidance Do Not Provide Clear and Unambiguous Standards as to the Frequency and Duration of Therapy.

The government states that "Defendants contend that the 'reasonable and necessary' standard is so vague and ambiguous that the United States cannot establish falsity 'as a matter of law.'" Opp'n 9-10. Defendants never made that argument. Defendants actually argued that what is "reasonable and necessary" is vague and ambiguous with regard to the allegations in this Complaint regarding determinations of the frequency and duration of therapy minutes. *See* Mot. 17-20. Defendants' position is entirely consistent with the regulatory scheme. *See* Mot. 13-15. The government is not without recourse if it disagrees over clinical determinations. It can and frequently does administratively review and disallow claims or portions of claims. Thus, the purposeful vagueness and ambiguity of clinical standards, as well as the express provision that clinical disagreements are not false, preclude FCA liability absent allegations of specific deviations from an unambiguous rule. *See, e.g.*, *United States ex rel. Ketroser v. Mayo Found.*,

[5] The government also ignores the critical role of the physician in ongoing therapy after the initial order. *See* 42 C.F.R. § 483.40(c) (each patient must be seen by a physician at least once every 30 days for the first 90 days after admission and at least every 60 days thereafter); 42 U.S.C. § 1395f(a)(2)(B); 42 C.F.R. §§ 409.31(b), 424.20(a) (providing for a physician's certification that indicates the patient: (1) requires skilled nursing or skilled therapy services (or both) on a daily basis; (2) the daily skilled services can only be provided in a SNF on an in-patient basis; and (3) the services provided address a condition for which the patient received treatment during a qualifying hospital stay).

729 F.3d 825, 832 (8th Cir. 2013); *Hagood v. Sonoma Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996); *Prabhu*, 442 F. Supp. 2d at 1026.[6]

The government has admitted to the lack of clarity in skilled rehabilitation standards in the settlement in *Jimmo v. Sebelius*, No. 11-0017 (D. Vt. Oct. 16, 2012) (Mot. Ex. C), and recognized the need to revamp and clarify applicable standards. Indeed, CMS recognized the inherent ambiguity in promulgating a regulation that protects such clinical disagreements. *See* 42 C.F.R. § 483.20(j)(2). Further, the government's only argument that the standard is clear is its complete mischaracterization of the Medicare Benefit Policy Manual ("MBPM"), Ch. 8, § 30. Opp'n 9-10. What the government claims to be the definition of "reasonable and necessary" with respect to skilled rehabilitation therapy is in fact the definition applicable to whether a patient is eligible for skilled care generally, which the government has already conceded with respect to the patients in this case. Specifically, with respect to skilled physical therapy, once the patient qualifies for skilled care, the guidance as to what is reasonable and necessary is circular and provides no actual definition at all. *See* MBPM Ch. 8, 30.4.1.1. ("The services must be reasonable and necessary for the treatment of the patient's condition; this includes the requirement that the amount, frequency, and duration of the services must be reasonable."). This is precisely the reason why CMS explicitly stated in its regulations that clinical disagreements are not false statements.

Finally, purported corporate pressure does not establish scienter, especially in the context of an unreasonable interpretation of the ambiguous regulations. *See Lawson*, 2015 WL 1541491, at *13 (holding that tracking and goal setting for UH RUG levels prudent business practice, but

[6] Defendants' position is not that standards do not exist or that the standard is "unknown". Opp'n 10. Rather, here, (1) no standard is pled, and (2) even if a standard had been pled, it would not be susceptible to second guessing through an FCA action when the allegations merely assert challenges to clinical determinations as to the frequency and duration of skilled therapy.

not fraud); 42 C.F.R. § 483.20(j)(2). As to the government's "specific examples," Defendants established in their Motion that the government's two examples of the purported submissions of claims "where the physician had not certified that the patient needed the particular type of treatment" were demonstrably false and that all therapy services were ordered by a physician.[7]

III. THE GOVERNMENT'S "REPRESENTATIVE EXAMPLES" ARE NOT SUFFICIENTLY PLED AND HIGHLIGHT THAT EACH PATIENT'S THERAPY IS SUBJECTIVE AND NOT SUBJECT TO CLEAR AND UNAMBIGUOUS STANDARDS.

The government contends that the Complaint alleged sufficient information to put the Defendants "on notice" of the conduct alleged. Opp'n 8. The government cannot salvage the Complaint by lowering the pleading bar to a less rigorous Rule 9(b) standard – one of bare "notice." Opp'n 12-13. Neither does reliance on *United States ex rel. Badr v. Triple Canopy, Inc*. 775 F.3d 628 (4th Cir. 2015), Opp'n 14, provide legal support for such an argument. Instead, *Badr* is consistent with Rule 9(b)'s requirement that the government provide the "who, what, when, where, and how" of claims for fraud. *Id*. at 634 (an FCA plaintiff must, at a minimum, describe the time, place, and contents of the false representations); *see also United States ex rel. Ahumada v. NISH*, 756 F.3d 268, 280-81 (4th Cir. 2014).[8]

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[7] The medical records actually indicate that Patient C received previously ordered therapy for one day, when on the same day, the physician ordered palliative care. Compl. ¶ 172. The Complaint does not allege that the physician order for Patient D's hospice care was issued and/or known to the therapist at the time of the therapy or that Patient D elected hospice care prior to receipt of the previously ordered therapy. Compl. ¶ 175. Further, the attached additional portions of the medical records for Patient G demonstrate that the government's contention is false. *See* Mot. 24 n.21, Ex. D.

[8] *See also United States ex rel. Frazier v. IASIS Healthcare Corp*., 812 F. Supp. 2d 1008, 1016-18 (D. Ariz. 2011*); Maa v. Ostroff*, No. 12-0020, 2013 WL 1703377 (N.D. Cal. Apr. 19, 2013). Additionally, the government's reliance on *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), for the lowering of its pleading standard is misplaced, as courts in this Circuit have distinguished and limited that case and articulated the applicable Rule 9(b) standard. *E.g., United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc*., 707 F.3d 451, 457-58 (4th Cir. 2013); *United States ex rel. McLain v. KBR, Inc.*, No. 08-499, 2013 WL 710900, at *9-10 (E.D. Va. Feb. 27, 2013).

With respect to Patients A – H, the government effectively seeks to amend the Complaint by pronouncements of law and regulations that are not pled in the Complaint and also are either wrong or are not supported by any authority. For example, the government contends that an October 2011 final rule means that Defendants were required by regulation to "justify" how group therapy related to the plan of care even prior to implementation of that rule, and even though no such regulation existed at the time of Patient A's care. *Compare* Opp'n 13-14, *with* Mot. 13-14.[9] As to Patients B, E, and F, the government states that it does not have to plead the existence of a statute or regulation requiring defendants to do what the government asserts it failed to do. Opp'n 14-15. But the government misses the point of the argument, which is that the government failed to plead any such statutes or regulations because *they do not exist*. Instead, the government simply announces that therapy is unreasonable and unnecessary and concocts alleged paperwork and other requirements to support its theory of the case.[10] As to Patient B, there are no regulations prohibiting fluctuations, alleged to be "ramping," that would render the claim objectively false – indeed, the regulatory guidance recognizes and provides for

[9] The regulatory history demonstrates that the late 2011 documentation requirement for group therapy was viewed by providers as new. *See* 76 Fed. Reg. 26,364, 26,387 (May 6, 2011); 76 Fed. Reg. 48,486, 48,516-17(Aug. 8, 2011) ("Several commenters supported the clarification of our expectations for documenting group therapy services. . . Others expressed concern that we proposed new and stricter guidelines for documenting group therapy. Some commenters stated that requiring a therapist to document why a specific mode of therapy was chosen for a patient would create an undue burden on the therapist."). Further, if this requirement had been in place prior to October 1, 2011, there would have been no reason for CMS to provide training for SNF providers on how to document group therapy. *See*, *e.g.*, MDS 3.0 and RUG-IV, Updates and Training for FY 2012 (Aug. 23, 2011), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/RUGIVEdu12.html.

[10] For example: as to Patient B, requiring documentation of clinical reasons to support increase in therapy during assessment periods (Compl. ¶ 153); as to Patient E, requiring documentation regarding indication for use of modalities even though specifically ordered by a physician (Compl. ¶ 182); as to Patient F, requirement not to provide therapy where patient was lethargic (Compl. ¶ 187).

such fluctuations. *See* 64 Fed. Reg. 41,644, 41,668 (July 30, 1999) (providing that "the payment rate, once established, is guaranteed for as long as the beneficiary's care needs continue to fall within the range of covered care, even if the specific acuity of the beneficiary's care needs within this range decreases; thus, the SNF can continue to receive the higher payment rate for such a beneficiary's covered care up to the next assessment"). Similarly, as to patients E and F, the government cites to no authority or objective standard to support that modalities were not reasonable and necessary, nor does the government respond to the regulation that expressly provides that modalities are appropriate skilled therapy. Mot. 24. Now recognizing the insufficiency of these allegations, the government suggests that there were no clinical reasons supporting the use of modalities at all.[11] Aside from not having any factual basis to do so, the government cannot amend its complaint in its Opposition. *Davis v. Hampton Pub. Sch. Dist.*, No. 09-0004, 2009 WL 8652920, at *2 (E.D. Va. June 22, 2009) (a "plaintiff cannot amend his Complaint by altering his facts in his brief in response to the motion to dismiss"), *aff'd*, 352 F. App'x 780 (4th Cir. 2009).

The government fails to establish Patients C and D as representative examples of a scheme to provide therapy to patients too ill to need or legitimately receive therapy.[12] Opp'n 16-17. The Complaint fails to allege why certain therapy minutes were reasonable and necessary while others were not, how it made such determinations, and against what measure reasonableness is judged. That is, neither the Court nor the Defendants know from the Complaint whether the government determined that there must be "measurable improvement," or

[11] There is no legal support cited for the proposition that the lack of clinical justification for modalities evidences "Defendants' desire to increase RUG level payment," nor is there such authority. *See* Opp'n 15-16.

[12] The Opposition concedes that Patient D had not elected hospice care and remained eligible for skilled therapy but stands by the government's contention that certain therapy minutes were not reasonable and necessary. Opp'n 16.

the incorrect higher legal standard used by the government in *Lawson* of "significant practicable improvement," or some other standard yet to be disclosed. The Complaint provides no regulatory citation to any objective standard applicable to therapy for patients with these particular factual circumstances, and as such, has not adequately pled knowing fraud. *See, e.g.*, *Frazier*, 812 F. Supp. 2d at 1016-18; *Maa*, 2013 WL 1703377, at *19-20.

Further, the government fails to overcome the pleading deficiencies with respect to Patients G and H and alleged unreasonable speech therapy. First, as to Patient G where the medical records show the government's allegation that no order for speech therapy existed was demonstrably false, the government pronounces in its Opposition that, notwithstanding the order, the patient *still* did not need speech therapy. Opp'n 17-18.[13] With respect to Patient H, who also had a physician's order for speech therapy, the government now contends that the physician order was wrong and that Defendants committed fraud by following it. Opp'n 18. No such allegation is contained in the Complaint. *See* Compl. ¶ 195.

In addition to failing to provide actual examples of fraud under Rule 9(b) pleading standards, the government's over-simplified, excerpted, and mischaracterized examples establish that skilled rehabilitation therapy requires a case-by-case analysis based on an individual patient assessment by the treating medical and clinical professionals. They further demonstrate that "reasonable and necessary" is vague and ambiguous with respect to determining the appropriate amount of therapy minutes and the government has not pled any objective standard by which to judge appropriateness – apparently, the government believes it is sufficient if it *knows it when it sees it*.

[13] The government then highlights the only allegations regarding unskilled therapy, supervision of Patient G eating, *id*., but does not allege any facts to support that eating observation is unskilled, which would satisfy the government's pleading obligation to allege how this violates any objective regulatory standard. *See Ahumada*, 756 F.3d at 280-81.

IV. THE COMPLAINT FAILS TO ALLEGE FACTS SUPPORTING A CAUSAL LINK BETWEEN THE ALLEGED CORPORATE SCHEME AND THE SUBMISSION OF ANY FALSE CLAIMS.

The government argues incorrectly that it is not under any obligation to allege facts demonstrating a link between Defendants' purported fraudulent corporate scheme and the submission of a single false claim. Opp'n 18. It simply pronounces, without any case authority, that it "has no such obligation." Opp'n 18. But the government ignores the plain language of the FCA, requiring causation, which supports that the government must plead a link between an alleged corporate scheme and submittal of false claims. In order to plead a claim under the FCA, one must allege that a false statement or false course of conduct was carried out with requisite scienter which caused a false claim to be submitted to the government for payment. *See* 31 U.S.C. § 3729(a)(1)(A) and (B). To assert a claim under the plain language of the FCA, it is not enough to allege merely that a health care provider developed a corporate scheme to disregard government regulations or encourage improper internal policies, it must also allege that the provider knowingly submitted false claims for reimbursement as a result of such acts.

Defendants cited several cases in its Motion that establish that in order to plead a FCA claim, one cannot simply allege the existence of a corporate scheme. *See* Mot. 25-26. The government must plead the existence of a corporate scheme and that the scheme caused the submission of false claims. Otherwise, a complaint is "missing the final link in the chain of causation." *United States ex rel. Hagood v. Riverside Healthcare Ass'n, Inc.*, No. 11-0109, 2015 WL 1349982, at *11 (E.D. Va. Mar. 23, 2015) (citation omitted). Here, the government pleads no facts to demonstrate a link between the alleged false claims and purported corporate pressure. Indeed, nowhere in the Complaint does the government allege that anyone on behalf of Defendants knowingly submitted false claims for reimbursement under the alleged corporate pressure or scheme to do so. Further, the Complaint does not allege that any physician, therapist

or employee who had contact with the identified patients had any knowledge of or role in the alleged corporate scheme to defraud. Nowhere in the Complaint are there any facts showing that physicians, therapists or employees who actually treated the patients who are the subject of the Complaint were pressured or encouraged to over-deliver therapy to these patients. Instead, the Complaint contains unsubstantiated conclusory allegations that such pressure was applied, without any link to the actual claims submitted to the government. The Complaint fails to plead sufficient causation absent more specific allegations demonstrating a link between the alleged corporate scheme and false claims.

V. THE GOVERNMENT'S ATTEMPTED RECASTING OF THE COMPLAINT IN ITS OPPOSITION AS TO SPECIFIC INDIVIDUALS' SCIENTER FAILS TO OVERCOME THE COMPLAINT'S DEFICIENCIES.

The Complaint fails to identify any doctor who ordered therapy or any particular therapist who knowingly provided therapy in violation of a legal or professional standard or any employee of any Defendant who submitted or possessed independent knowledge of the submission of a single false claim. In fact, the government argues incorrectly that it is not required to allege such facts. Opp'n 22. Instead, to support its FCA claims, the Complaint attempts to allege that the collective knowledge of certain Defendants' employees formed the basis for the requisite scienter. Merely alleging individuals' collective knowledge of a purported corporate scheme to defraud and resulting false claims is not sufficient to form the basis for scienter in a FCA case. *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010); *see also United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003). Rather, actual knowledge of false claims by a specific employee or therapist of any Defendant must be pled in order to satisfy the scienter requirement. *See Sci. Applications Int'l Corp.*, 626 F.3d at 1274. Otherwise, a plaintiff would be able to allege scienter simply by "piecing together scraps of 'innocent' knowledge held by various corporate officials, even if

those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." *Id*. at 1275 (citing *Harrison*, 352 F.3d at 981 n.9).

The Complaint does not allege that any individual on behalf of Defendants submitted a false claim, was aware of a particular false claim, or acted with knowledge that the services provided to Patients A-H were unnecessary or unreasonable. Instead, the government attempts to embellish allegations in the Complaint in an effort to allege the requisite scienter. Although, in an effort to demonstrate that Defendants knowingly submitted false claims, the Opposition now focuses on the actions of three of Defendants' employees, Messrs. Pagoaga, Lazarus, and Guillard, *see* Opp'n 21-25, none of these paragraphs relating to these individuals allege facts that these individuals knew about the submission of any false claim or that therapists were yielding to corporate pressure in over-delivering or providing improper services to any patients, let alone to the patients that are the subject of this case. *See* Compl. ¶¶ 31-32, 35, 76-77, 80-82, 93, 95, 105, 109, 112, 114, 127, 136, 141, 203, 206-07, 210. Rather, the knowledge the government alleges that these individuals possessed regards only the discussion of corporate metrics, the conducting of audit reports, complaints of exiting employees, and the performance of various other facets involved in the managing of a complex, multi-faceted, nationwide enterprise business.[14] Because the Complaint fails to allege facts that Messrs. Pagoaga, Lazarus, or Guillard pressured or influenced any therapists into actually fraudulently over-delivering therapy and submitting false claims, the government, again presumably seeking to supplement the Complaint, raises the new allegation in its Opposition that these individuals knew of the submission of false claims or

[14] Paragraphs 206, 207, and 210 of the Complaint allege that Mr. Lazarus and Mr. Pagoaga were advised that one or two therapists in 2008 and 2009 raised the issue of corporate pressure. But there is no allegation that either Mr. Lazarus or Mr. Pagoaga failed to take appropriate action with respect to this information. Moreover, there is no allegation that Mr. Lazarus or Mr. Pagoaga were informed that any therapist actually engaged in fraudulent over-delivery of therapy.

acted in reckless disregard of the truth or falsity of claims. *See* Opp'n 24.[15] These conclusory statements are not supported by the allegations in the Complaint, nor can they save the deficiencies of the Complaint. Accordingly, the Court should not consider any new allegations made against these named individuals through the government's Opposition.

VI. THE ALLEGATIONS AS TO EACH CORPORATE DEFENDANT FAIL TO SATISFY APPLICABLE PLEADING STANDARDS.

In responding to Defendants' argument that it failed to satisfy Rule 9(b) as to each Defendant's purported conduct, the government concedes that "a plaintiff must allege claims with particularity as to each defendant," but then suggests that grouping the Defendants as one satisfies Rule 9(b). Opp'n 25-27. In *Juntti v. Prudential-Bache Securities, Inc.*, 993 F.2d 228, at *2 (4th Cir. 1993), the Fourth Circuit expressly held that allegations referring to the "defendants" collectively, rather than to actions of specific defendants, failed to provide either sufficient notice of the alleged fraud *or* sufficient protection from baseless allegations. The government's allegations here engender the same uncertainty, as the government contends that "all of the Defendants undertook the actions" described in the Complaint, while admitting that the defendants were involved "[a]t different times" and in different capacities. Opp'n 25-26.

The government next contends that it satisfied Rule 9(b) because the allegations in the Complaint apply to all defendants acting "in concert." The Complaint does not allege a conspiracy claim *under* § 3729(a)(1)(C), or even that the Defendants engaged in collusive conduct. For its premise, the government cites only its own allegations of corporate affiliation to support its claim of "in concert" activity, which allegations contain no references to fraudulent actions taken in concert. *See* Opp'n 25-26. Even if it had pled allegations of collusive activity,

[15] These allegations are new and unsupported by any facts alleged in the Complaint and therefore, should be excluded. *See White v. Jamaludeen*, No. 11-507, 2012 WL 1957583, at *n.1 (E.D. Va. May 29, 2012) ("[F]actual allegations contained in legal briefs or memoranda are treated as matters outside the pleadings for purposes of 12(b)(6)") (citations omitted).

such allegations still would be insufficient "without specifically alleging which defendant was responsible for which act." *Juntti*, 993 F.2d 228, at *2 (allegations that "Defendants, together with [their] agents . . . engaged in a scheme, practice or course of business to manipulate the market" failed to plead particularized allegations against any defendant).[16]

Finally, the government argues that the Defendants are not entitled to the protections of Rule 9(b) because they shared corporate parents and mailing addresses and retained the same defense counsel in this action, and thus should be deemed "one unified entity." *See* Opp'n 25-26. But the government offers no grounds for disregarding Defendants' separate corporate identities for these reasons. The sole authority cited for this extreme argument is *United States ex rel. Carter v. Halliburton Co.*, No. 08-1162, 2009 WL 2240331 (E.D. Va. July 23, 2009),[17] which does not cure the governments pleading deficiencies.[18]

VII. THE GOVERNMENT'S UNJUST ENRICHMENT AND PAYMENT BY MISTAKE CLAIMS ARE NOT SUFFICIENTLY PLED.

The government argues incorrectly that its unjust enrichment and payment by mistake claims are not subject to the heightened pleading requirements of Rule 9(b). Opp'n 27-28. As

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[16] *See also Devaney v. Chester*, 709 F. Supp. 1255, 1264 (S.D.N.Y. 1989) ("Bald allegations, as here, that a defendant acted 'in concert' with another are clearly insufficient to state a claim for conspiracy liability under Rule 9(b)."); *Breckley v. Amway Corp.*, No. 6:89-540-17, 1989 WL 140397, at *5 (D.S.C. Aug. 24, 1989) ("Breckley's bare allegations that the defendants acted in concert obviously do not reach the level of pleading required by Rule 9(b).").

[17] In *Carter*, the Court excused a relator's inability to identify which defendant ultimately bore legal responsibility for the allegedly false statements where the relator not only alleged that each defendant submitted false claims or caused false claims to be submitted, but also identified "both the entity directly submitted the alleged false statements to the Government . . . and the specific people writing the false statements." 2009 WL 2240331, at *15.

[18] Although the government contends that the "reporting structure established by Defendants appears to be purposely complex," Opp'n 26, the Complaint is devoid of allegations of such complexity or intention to obfuscate. The government cites the paragraphs of its Complaint which describe the Defendants' management structure in detail, further confirming that the government's four years of pre-litigation investigation provided it with sufficient information to present particularized allegations if, in fact, it had uncovered particularized evidence of fraud.

the authorities cited in the Motion establish, claims for unjust enrichment or payment by mistake like the ones filed by the government are indeed subject to the heightened Rule 9(b) pleading standard. *See* Mot. 29-30; *Silverman Partners, L.P. v. First Bank*, 687 F. Supp. 2d 269, 288 (E.D.N.Y. 2010) (unjust enrichment must be pled under heightened Rule 9(b) pleading standard when premised on a claim that one has mislead another in order to abscond with their money). The government has not made any effort to rebut these cases. Instead the government cites *United States v. Gericare Med. Supply Inc*., No. 99-0366, 2000 WL 33156433 (S.D. Ala. Dec. 11, 2000) to support its argument that the heightened Rule 9(b) standard does not apply to unjust enrichment claims. However, the *Gericare* court found that the Rule 9(b) standard should apply to the unjust enrichment claim in that case. For the same reasons the government's Counts I and II should be dismissed, its claims for unjust enrichment and payment by mistake should be dismissed as well. *See Lawson*, 2015 WL 1541491, at *14 (allegations of unjust enrichment and mistaken overpayment in connection with alleged false claims involving unnecessary services are derivative of plaintiff's FCA claims and should be dismissed on the same grounds as the dismissal of the FCA claims).

VIII. CONCLUSION

For the foregoing reasons and those stated in the Motion, Defendants respectfully request that the Court grant the Motion and dismiss the Complaint.

Dated: August 28, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August, 2015, the foregoing was electronically filed with the clerk of court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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